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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/690,173 | 10/16/2000 | Karen W. Shannon | 10990638-1 | 2834 |

7590

05/08/2002

IP Administration
Legal Department 20BN
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EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/690,173

Applicant(s)

SHANNON, KAREN W.

Examiner

Janet Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32-48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 32-37 and 39-40 remain rejected and claims 38, and 41-48 are under 35 U.S.C. 102(e) as being anticipated by Wang et al, and claims 32-36 and 39-40 remain rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al. for the reasons of record set forth in the Official Action mailed 9-26-2001.

Applicant's arguments filed 2-12-2001 have been fully considered but they are not persuasive. Applicants traverse the instant rejections on the grounds that Examiner improperly discounted the relationship between the instructions recited in the kits of the instant invention, and the overall patentability of the claimed invention. Applicants assert that courts treat instructions for use, e.g., in the form of printed matter, as a separate element to be accorded patentable weight just like any other recited element. Applicants cite *In re Gulack*, 217 USPQ 401 (1983), and *In re Miller*, 57 CCPA 809, 418 F.2d 1392, 164 USPQ (BNA) 46, to support their conclusion that since the instructions are functionally related to the other kit elements of the present invention, they must be accorded patentable weight because they tell how to use the other kit elements that is different from the prior art.

First it is noted that the facts upon which the *In re Gulack* and *In re Miller* cases were determined are distinct from those facts in the present situation. In the *In re Gulack* and *In re Miller* cases, the printed matter was directly printed upon the claimed invention, wherein the mere presence of the printed matter conferred a novel and unobvious functionality to the claimed

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invention. The printed material of the kit of the instant invention, do not directly affect any material properties of the remaining contents of the kit. The instructions merely provide an intended use of the remaining contents of the kit, which requires manipulation of the contents of the kit. The kit absent the manipulations directed by these instructions is clearly anticipated by the prior art.

Assuming, *arguendo*, that the instructions of the present invention functionally modified the claimed invention, one of skill in the art would recognize that the disclosures of the Wang et al. and Phillips et al. references can be used as a set of instructions to use the contents of the kit of the present invention in a method of mRNA amplification.

As stated in the prior Office Action, Wang et al. provides kits for use in a method for mRNA amplification, where such kits may comprise containers, each with one or more of the various reagents (typically in concentrated form) utilized in the methods, including, for example, buffers, the appropriate nucleotide triphosphates, reverse transcriptase (preferably M-MLV RT lacking RNaseH activity), DNA polymerase (HTLV-1, HIV, BLV, Taq and Tth), RNA polymerase (e.g. T7), one or more primer complexes of the present invention (e.g., poly(T) or random primers linked to a promoter reactive with the RNA polymerase), and a set of instructions will also typically be included.

Additionally, Phillips et al. discloses compositions for the intended use of linear amplification of mRNA comprising the use of the contents of the kit recited in the instant claims particularly wherein said kit comprises: an oligonucleotide comprising an RNA polymerase promoter sequence, at least one polymerase, further comprising an RNA polymerase (e.g., T7).

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Applicant's arguments do not take the place of evidence clearly distinguishing the claimed invention from the prior art.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.
Examiner
Art Unit 1635

JLE
May 1, 2002



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600